35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo et al (U.S. Patent No.488,038) in combination with Daniels (U.S. Patent No. 4,000,261).

Kondo et al disclose that dikekacin and arbekacin derivatives are against drug-resistant bacteria such as MRSA (column 1, lines 54-62) but do not disclose the use of 5-epi-derivatives of said compounds. However, since 5-epi-derivatives of aminoglycosides were known in the art at the time the claimed invention was made as

disclosed by Daniels, it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to modify the compounds disclosed by Kondo et al in accordance with the teaching by Daniels because such a person would have expected the resulting compounds to possess similar activity.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacterial infections, does not reasonably provide enablement for treating or preventing an infectious disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

(A) The breadth of the claims.

The clam encompasses treating and preventing all types of infectious diseases, including viral infections. Further, the broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cell of a host. There is no evidence that such entry would be prevented.

(B) The state of the prior art.

Aminoglycosides are known antibacterial agents.

(C) The amount of direction provided by the inventor.

The disclosure that the claimed compounds are useful against bacterial infections is clearly not commensurate with the full scope of the claimed invention.

(D) The existence of working examples.

The working examples are limited to the activity against MRSA bacterial infection.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict against which additional infectious diseases the claimed compounds would be useful, it would take an undue amount of trial and error to test the claimed compounds against a large number of infectious diseases, including viral infections.

Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-26 provide for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 25-26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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